UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

MAR 2 1 2007

REPLY TO THE ATTENTION OF:

AE-17J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Brian Brown, Project Engineer
Eli Lilly and Company
Lilly Corporate Center
893 South Delaware
Indianapolis, Indiana 46285

Re: Finding of Violation
Eli Lilly and Company
Lilly Technology Center
Indianapolis, Indiana

Dear Mr. Brown:

This is to advise you that the United States Environmental Protection Agency (U.S. EPA) has determined that Eli Lilly and Company (Lilly or you) at 1555 South Harding Street, Indianapolis, Indiana, is in violation of Section 112 of the Clean Air Act (the Act), 42 U.S.C. § 7412. Specifically, Lilly has violated the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG, the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks at 40 C.F.R. Part 63, Subpart H (the Hazardous Organic NESHAP), and EPA Reference Method 21 at 40 C.F.R. Part 60, Appendix A (Method 21), as provided below. We are today issuing to you a Finding of Violation (FOV).

Section 112(d) of the Act requires U.S. EPA to promulgate maximum achievable control technology (MACT) standards for particular industrial sources that emit one or more of the hazardous air pollutants (HAPs) listed in Section 112(b) of the Act in significant quantities. For pharmaceutical manufacturing operations, U.S. EPA promulgated the NESHAP for Pharmaceuticals Production (the Pharma-MACT) on April 2, 1997. The Leak Detection and Repair (LDAR) provisions of the Pharma-MACT incorporate the Hazardous Organic NESHAP (the HON), which

U.S. EPA promulgated on December 31, 1992. Lilly has violated the following LDAR provisions of the Pharma-MACT and the HON:

1) Lilly must identify equipment subject to the LDAR provisions such that it can be distinguished readily from equipment that is not subject.

2) Lilly must monitor equipment subject to the LDAR provisions per Method 21.

3) Lilly must return each pressure relief device subject to the LDAR provisions to below 500 parts per million above background no later than 5 calendar days after a pressure release.

4) Lilly must use the equation set forth in 40 C.F.R. § 63.174(i)(2) to calculate the percent of leaking connectors for use in determining connector monitoring frequency.

U.S. EPA finds that Lilly has violated the requirements listed above. Section 113 of the Act gives us several enforcement options to resolve these violations, including: issuing an administrative compliance order, issuing an administrative penalty order, bringing a judicial civil action, and bringing a judicial criminal action. The option we select, in part, depends on the efforts taken by Lilly to correct the alleged violations and the timeframe in which you can demonstrate and maintain continuous compliance with the requirements cited in the FOV.

Before we decide which enforcement option is appropriate, we are offering you the opportunity to request a conference with us about the violations alleged in the FOV. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply, and the steps you will take to prevent future violations. Please plan for your facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

The U.S. EPA contact in this matter is Ray Cullen. You may call him at (312) 886-0538 if you wish to request a conference. U.S. EPA hopes that this FOV will encourage Lilly's compliance with the requirements of the Act.

Sincerely yours,

Stephen Rothblatt, Director ACTING
Air and Radiation Division

Enclosure

cc: Craig Henry, Chief
Office of Enforcement Air Section
Indiana Department of Environmental Management
100 North Senate Avenue, Room 1001
Indianapolis, Indiana 46206-6015

United States Environmental Protection Agency
Region 5

IN THE MATTER OF: Eli Lilly and Company Indianapolis, Indiana Proceedings Pursuant to the Clean Air Act, 42 U.S.C. §§ 7401 et seq.	)))))))))	FINDING OF VIOLATION EPA-5-07-IN-06

FINDING OF VIOLATION

Eli Lilly and Company (Lilly or you) owns and operates a chemical plant at 1555 South Harding Street, Indianapolis, Indiana, referred to as the Lilly Technology Center (LTC). The LTC has been a major source as defined in Section 112(a) of the Clean Air Act (the Act) since before October 21, 2002. The BHI, KPB, r-Glucagon, Vanco, and Forteo processes at the LTC have been producing pharmaceutical products and have been processing, producing, or using organic hazardous air pollutants (HAPs) since that date. Therefore, as of October 21, 2002, LTC has been an affected source subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG (the Pharma-MACT). The Leak Detection and Repair (LDAR) provisions of the Pharma-MACT incorporate the National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks at 40 C.F.R. Part 63, Subpart H (the Hazardous Organic NESHAP).

The United States Environmental Protection Agency (U.S. EPA) is sending this Finding of Violation (FOV) to you for failing to 1) identify equipment subject to the LDAR provisions such that it can be distinguished readily from equipment that is not subject; 2) monitor equipment subject to the LDAR provisions per Method 21; 3) return each pressure relief device subject to the LDAR provisions to below 500 parts per million (ppm) above background no later than 5 calendar days after a pressure release; and 4) correctly use the equation set forth in 40 C.F.R. § 63.174(i)(2) to calculate the percent of leaking connectors for use in determining connector monitoring frequency.

You may request a conference with us to discuss the violations alleged in the FOV. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply, and the steps you will take to prevent future violations. Please plan for your facility's technical and management personnel to take part in these discussions. You may have an attorney accompany and represent you at this conference.

Explanation of Violations

1. The regulatory authority and facility requirements relevant to this FOV are as follows:

    a. Section 112(d) of the Act authorizes U.S. EPA to promulgate regulations for particular industrial sources that emit one or more of the HAPs listed in Section 112(b) of the Act in significant quantities.

    b. Pursuant to Section 112(d) of the Act, U.S. EPA promulgated the Pharma-MACT on April 2, 1997. The owner or operator of an existing affected source must comply with the provisions of this subpart no later than October 21, 2002, as required under 40 C.F.R. § 63.1250(f)(1).

    c. The Pharma-MACT, at 40 C.F.R. § 63.1250(a)(1), defines an affected source as a pharmaceutical manufacturing operation that: a) manufactures a pharmaceutical product; b) is located at a plant site that is a major source as defined in Section 112(a) of the Act; and c) processes, uses, or produces HAPs.

    d. Pursuant to Section 112(d) of the Act, U.S. EPA promulgated the Hazardous Organic NESHAP (the HON) on December 31, 1992. The owner or operator of an affected source under another subpart in 40 C.F.R. Part 63 that references this subpart must be in compliance by the date specified in that subpart, as required under 40 C.F.R. § 63.161.

    e. The LDAR provisions of the Pharma-MACT and the HON apply to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-

vent systems that are intended to operate in organic HAP service 300 hours or more during the calendar year, as stated under 40 C.F.R. §§ 63.1255(a)(1) and 63.160(a), respectively.

f. The Pharma-MACT and the HON, at 40 C.F.R. §§ 63.1251 and 63.161, respectively, define equipment in organic HAP service as equipment that either contains or contacts a fluid that is at least 5% by weight of total organic HAPs.

g. The Pharma-MACT, at 40 C.F.R. § 63.1255(a)(7), requires the owner or operator of an affected source to identify equipment subject to the LDAR provisions such that it can be distinguished readily from equipment that is not subject.

h. The Pharma-MACT, at 40 C.F.R. § 63.1255(b)(4), requires the owner or operator of an affected source to comply, in part, with Sections 63.174 and 63.180.

i. The HON, at 40 C.F.R. § 63.174(a)(1), requires the owner or operator of a process unit subject to the HON to monitor connectors in gas/vapor and light liquid service subject to the LDAR provisions by the method specified in Section 63.180(b).

j. The HON, at 40 C.F.R. § 63.161, defines a process unit, in part, as a process subject to another subpart in 40 C.F.R. Part 63 that references the HON.

k. The HON, at 40 C.F.R. § 63.180(b)(1), requires the owner or operator of an affected source to comply with the monitoring procedures and requirements of Method 21 of 40 C.F.R. Part 60, Appendix A.

l. Method 21, at 40 C.F.R. Part 60, Appendix A, Section 8.3.1, requires the owner or operator of an affected source to slowly sample the interface of a component where leakage is indicated until the maximum meter reading is obtained.

m. The Pharma-MACT, at 40 C.F.R. § 63.1255(b)(3), requires the owner or operator of an affected source to comply, in part, with Section 63.165.

n. The HON, at 40 C.F.R. § 63.165(b)(1), requires the owner or operator of an affected source to return a pressure relief device in gas/vapor service subject to the LDAR provisions to a condition indicated by an instrument reading of less than 500 ppm above background no later than 5 calendar days after a pressure release.

o. The HON, at 40 C.F.R. § 63.174(i)(2), requires the owner or operator of an affected source to calculate the percent of leaking connectors for use in determining connector monitoring frequency using the following equation:

$\%\ C_L = [(C_L - C_{AN})/(C_t + C_C)] \times 100$, where

$\%\ C_L$ = Percent leaking connectors as determined through periodic monitoring required in paragraphs (a) and (b) of Section 63.174;

C_L = Number of connectors, including nonrepairables, measured at 500 ppm or greater, by the method specified in Section 63.180(b);

C_{AN} = Number of allowable nonrepairable connectors, as determined by monitoring required in paragraphs (b)(3) and (c) of Section 63.174, not to exceed 2 percent of the total connector population, C_t;

C_t = Total number of monitored connectors, including nonrepairables, in the process unit; and

C_C = Optional credit for removed connectors = 0.67 x net number (i.e., total removed - total added) of connectors in organic HAP service removed from the process unit after the compliance date set forth in the applicable subpart for existing process units, and after the date of initial startup for new process units. If credits are not taken, then $C_C = 0$.

2. U.S. EPA inspected LTC on June 19-23, 2006 for compliance with the Pharma-MACT, particularly the LDAR provisions.

3. Lilly uses a tag-less system at LTC, where LDAR monitoring personnel use isometric drawings to identify components subject to the LDAR provisions.

4. During the inspection, some of the isometric drawings did not include all components subject to the LDAR provisions.

5. Lilly's failure to identify equipment subject to the LDAR provisions such that it can be distinguished readily from

equipment that is not subject is a violation of 40 C.F.R. § 63.1255(a)(7).

6. During the inspection, U.S. EPA conducted LDAR monitoring per Method 21 of the BHI, KPB, r-Glucagon, Vanco, and Forteo processes and found 4 out of 233 connectors in BHI, 4 out of 636 connectors in Vanco, and 4 out of 94 connectors in Forteo with leak readings above 500 ppm, resulting in leak rates of 1.72%, 0.63%, and 4.26%, respectively.

7. After the inspection, Lilly provided U.S. EPA with LDAR monitoring data from its LeakDAS database for LTC's Pharma-MACT affected processes from October 2002 through June 2006.

8. According to the LeakDAS data, Lilly found no connectors leaking in BHI or Vanco and found one connector leaking in Forteo from October 2002 through June 2006.

9. Lilly's failure to monitor connectors subject to the LDAR provisions per Method 21 is a violation of 40 C.F.R. § 63.174(a)(1), 40 C.F.R. § 63.180(b)(1), and Method 21, at 40 C.F.R. Part 60, Appendix A, Section 8.3.1.

10. During the inspection, U.S. EPA discovered two pressure relief valves in Vanco with leak readings above 500 ppm: 348051005, with a reading of 1,929 ppm, and 348053002, with a reading of 793 ppm.

11. According to the LeakDAS data, Lilly did not return the pressure relief valves to a level less than 500 ppm within 5 days after U.S. EPA discovered the leaks.

12. Lilly's failure to return the pressure relief valves to a level less than 500 ppm no later than 5 calendar days after U.S. EPA discovered the leaks is a violation of 40 C.F.R. § 63.165(b)(1).

13. During the inspection, U.S. EPA discovered four manways and a sight glass in KPB/r-Glucagon with leak readings above 500 ppm: 130080009, with a reading of 5,538 ppm; 130082001, with a reading of 2,100 ppm; 130197003, with a reading of 3,800 ppm; 130197004, with a reading of 800 ppm; and 130200003, with a reading of 2,000 ppm.

14. Lilly classifies manways and sight glasses as connectors in its LeakDAS database.

15. Lilly's inclusion of the manways and sight glasses as connectors in its LeakDAS database is a violation of the leak rate calculation equation set forth in Section 63.174(i)(2).

Environmental Impact of Violations

16. Violation of the NESHAP standards may cause serious health effects, such as birth defects and cancer, and harmful environmental and ecological effects.

MAR 2 1 2007

Date

AEJ/06

Stephen Rothblatt, Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Shanee Rucker, certify that I sent a Finding of Violation, No. EPA-5-07-IN-06, by Certified Mail, Return Receipt Requested, to:

Brian Brown, Project Engineer
Eli Lilly and Company
Lilly Corporate Center
893 South Delaware
Indianapolis, Indiana 46285

I also certify that I sent copies of the Finding of Violation by first class mail to:

Craig Henry, Chief
Office of Enforcement Air Section
Indiana Department of Environmental Management
100 North Senate Avenue, Room 1001
Indianapolis, Indiana 46206-6015

on the 22 day of March, 2007.

Shanee Rucker

Shanee Rucker,
Administrative Program Assistant
AECAS, (MI/WI)

CERTIFIED MAIL RECEIPT NUMBER: 7001 0320 0006 0198 9307